WEEKLY EPIDEMIOLOGICAL REPORT

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Is Victimization of the Rubella Vaccine Vindicated?

In the aftermath of the death following rubella vaccination at Matara, quality of the incriminated vaccine has been questioned in many quarters. Even those who are in the medical paternity were sceptical about its quality. This amply demonstrates the little comprehensibility of the quality assurance of vaccines used in the National Programme of Immunization (NPI) by various stakeholders in the health system.

The rubella infection in early pregnancy often results in miscarriages or still births. Congenital Rubella Syndrome (CRS) occurs in up to 85% of infants born to women who acquire rubella infection during the first trimester in pregnancy. In 1994 and 1995, there were epidemics of CRS in Sri Lanka. A survey done in 1995 also revealed that there were 275 cases of CRS in 1994 and a further 169 cases in the first four months of 1995. The burden of the disease (rubella and CRS) in the community and the public health impact thereof warranted its introduction in Sri Lanka. Based on the recommendation of the Advisory Committee on Communicable Diseases (ACCD), the rubella vaccine was introduced to the NPI in 1996.

From 1996 to 2001, using the high risk strategy, all females aged between 11-44 years were vaccinated with rubella vaccine with a view to controlling CRS in Sri Lanka. This was essential as it minimized the proportion of susceptible women for rubella infection in the potential child bearing age, the outcome being the reduction of CRS among new born children. However, the experience of other countries has demonstrated that even with 99% coverage of rubella vaccination among women in the child bearing age, CRS tends to occur as the virus circulates in the community among non immunized females and males. Therefore, gradually, countries need to adopt the universal strategy in which both males and females are vaccinated with a view to eliminating rubella. Thus, in 2001, Sri Lanka adopted the universal strategy of rubella vaccination by introducing the vaccine to both males and females at the age of 3 years as combined MR vaccine. Further, in 2001, to narrow the existing immunization gap, it was decided to administer rubella vaccine to all children irrespective of sex at the age of 8 years in schools instead of 11 years. From 2006 onwards all children are administered two doses of rubella vaccine at 3 years as combined MR and 13 years as monovalent rubella. Rubella vaccination was successful for a period well over a decade. However the death of a school child in Matara following anaphylaxis for rubella vaccine has prompted the doubt of the safety and the quality of the rubella vaccine in the minds of some despite over ten million doses being used over 12 years in the NPI.

As a departmental policy, all vaccines used in the NPI are purchased from the WHO pre qualified sources. This is no exception for the rubella vaccine. The World Health Organization has its own system for quality assurance of vaccines purchased by United Nations organizations. Such vaccines are called WHO pre qualified vaccines. There is an established procedure used by WHO for the initial evaluation of candidate vaccines and reassessment at regular intervals to ensure the quality of vaccines currently being used is continued. Accordingly, when the Epidemiology Unit submitted specifications for procurement of vaccines, it was highlighted that the offers should be made only by vaccine suppliers recommended by the WHO for bulk purchase by United Nations agencies. In addition to this, it was specified that the bidding vaccines should have a shelf life of 2 years at the time of dispatch, comply with gen-

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eral requirements for vaccines in the British or US pharmacopia , vaccine should meet the most recent requirements of the WHO at the time of bidding when tested by the methods outlined by the WHO. Further, it was highlighted that the product should preferably be from one batch and each batch should carry a certificate of analysis (lot release certificate) issued by a national control laboratory or by a laboratory accredited by a national control authority. Packaging was supposed to comply with WHO guidelines on international packaging and shipping of vaccines for EPI.

When the currently incriminated rubella vaccine was procured, the Epidemiology Unit as the main organization implementing the NPI submitted the above specifications to the Director Medical Supplies Division (MSD) to purchase 300000 doses .As per request made by the Director MSD, the State Pharmaceutical Corporation called for world wide tenders to supply rubella vaccine. There was one sole bidder to supply the rubella vaccine to the NPI and that was the Serum Institute of India. Based on the recommendations of the Chief Epidemiologist and the technical evaluation committee , the departmental procurement committee awarded the tender to the sole bidder. Serum Institute of India was, by no means, a stranger to the NPI. Out of the ten different types of vaccines used in the NPI , seven vaccines are manufactured and delivered to Sri Lanka by the Serum Institute. BCG, Dt, dT,DTwP,DTwP-HepB,Hep B (recombinant),Hib,TT,MR,MMR, measles , Rubella vaccines manufactured by the Serum Institute are WHO pre qualified vaccines.

As indicated in the Cosmetic Devices and Drugs (CDD) act which is the legal framework for providing safe and efficacious drug supply to the citizens of the island, only registered vaccines at the Cosmetic Devices and Drugs Authority (CDDA) are permitted to use in the NPI. Is the incriminated vaccine a registered product at the CDDA? The Serum Institute of India had submitted an application for registering the rubella vaccine at the CDDA in 2001. Incidentally, the registration which was valid for five years was granted on December 07, 2001.At the expiry of this period, the product was re-registered on December 7, 2006 for a period of another five years by a panel of experts of the Drug Evaluation Sub Committee (DESC).

The batch of the rubella vaccine purchased through the above tender was delivered in Sri lanka on 09.05.2008. The batch number was ZA 37X. Once a new batch of vaccines is delivered, the subsequent step taken by the national authority is the procedure called the "Lot Release" carried out by the national control laboratory (MRI). As biological drugs such as vaccines are complex molecules that cannot be chemically defined and because of the inherent variability of biological systems , each production run of a biological product , in this particular occasion a vaccine, can be considered unique. Therefore, the products are subject to scrutiny by national regulatory authorities on a lot by lot basis. The initial review of the lot is done during the licensing process when the methods of manufacture and testing and the consistency of production of several lots are evaluated. Lot release is a process of reviewing each individual batch of a licensed product before giving approval for releasing it to the market. It includes the review of manufacturer's production, quality testing data and may include laboratory testing by the national control laboratory. At the MRI, Standard Operating Procedures for lot release include reviewing summary protocol of the manufacturing steps and test results from the full manufacturing and control process and lot release certificate from the National Regulatory Authority of the country of origin (India in this case). This release is carried out by a globally trained staff under a consultant virologist (vaccinologist) at the MRI. There is a procedure to test the safety and sterility which is not done under normal circumstances unless there are specific indications. As such, safety and sterility tests were not applicable to the rubella vaccine under review in lot release .

These vaccines are stored at the central cold stores at the Epidemiology Unit until they are distributed to the Regional Medical Supplies Divisions(RMSD). The Epidemiology Unit has a sophisticated system of recording storage temperatures of the central cold stores and based on these, with a high degree of responsibility , it can be sated that the cold chain of the rubella vaccine in question was maintained to the highest degree. RMSD Matara had received 12 000 doses of the said rubella vaccine on 14.08, 02.10. 2008 and 26.02.2009. MOH office Matara has received 1000 doses on 09th and 13th March 2009. Sri Lankan NPI is unique in the sense that it has a wonderful system to track the status of maintaining the cold chain down to the delivery point. Tracking evidence indicates that the cold chain at the RMSD Matara and MOH office Matara was uninterrupted.

The supplier has provided vaccines to the NPI since 1998 and the rubella vaccine since 2001. During this period over five million doses of rubella vaccines have been used and there have not been previous complaints regarding the rubella vaccine. Surveillance information indicates that there was not a single case of CRS reported in 2007 and 2008 in Sri Lanka. By virtue of the procedures followed in procurement to delivery of the vaccine to the recipient , its pedigree of performance in terms of safety, effectiveness in the long period of use and empirical data on post vaccination disease burden, The Epidemiology Unit will be able to give the assurance that the rubella vaccine is safe for recipients. However, any medical intervention or use of a pharmaceutical involves a certain degree of risk. Modern medicine recommends it as the benefits far outweigh the risks. This risk benefit concept is also applicable to the rubella vaccine too. It is reported that every year around 4000 people die as a result of road traffic accidents. Does that mean that people refrain from using transport as risk is involved?. In a modern society, benefits such as luxury, convenience and quick movements associated with transport prompt people to use transport despite negative outcomes of road traffic accidents. Similarly, while accruing benefits such as elimination of CRS and resultant disabilities to the greater majority of people, rubella vaccine might give rise to very rare adverse effects in a minority of recipients. It will in no way stop the use of the rubella vaccine as the benefits of the vaccine to the individual, community and the country is enormous in comparison to the rare risk it poses to the recipients.

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Table 1: Vaccine-preventable Diseases & AFP

07th March - 13th March 2009 (11th Week)

Disease	No. of Cases by Province									Number of cases during current week in 2009	Number of cases during same week in 2008	Total number of cases to date in 2009	Total number of cases to date in 2008	Difference between the number of cases to date in 2009 & 2008
	W	C	S	N	E	NW	NC	U	Sab					
Acute Flaccid Paralysis	00	01 KN=1	00	00	00	00	00	00	00	01	00	14	17	-17.6%
Diphtheria	00	00	00	00	00	00	00	00	00	00	00	00	00	-
Measles	00	01	00	01	00	00	00	00	00	02	00	32	26	+23.0%
Tetanus	01	00	00	00	00	00	00	00	00	01	00	07	08	-12.5%
Whooping Cough	00	00	00	00	00	00	00	00	00	00	01	17	08	+112.5%
Tuberculosis	104	46	05	02	38	30	22	14	06	252	126	1762	1935	-08.9%

Table 2: Newly Introduced Notifiable Disease

07th March - 13th March 2009 (11th Week)

Disease	No. of Cases by Province									Number of cases during current week in 2009	Number of cases during same week in 2008	Total number of cases to date in 2009	Total number of cases to date in 2008	Difference between the number of cases to date in 2009 & 2008
	W	C	S	N	E	NW	NC	U	Sab					
Chickenpox	45	23	18	495	13	10	05	08	26	643	101	2841	1206	+135.6%
Meningitis	03 GM=1 CB=1 KL=1	01 KD=1	04 GL=1	00	01 BT=1	02 PU=2	04 AP=4	01 BD=1	01 KG=1	17	23	214	392	-45.5%
Mumps	01	02	03	07	00	01	02	04	08	28	38	405	476	-15.0%
Leishmaniasis	00	01 ML=1	08 MT=4 HB=4	00	00	00	04 AP=2 PO=2	00	00	13	Not available*	315	Not available*	-

Key to Table 1 & 2

Provinces: W: Western, C: Central, S: Southern, N: North, E: East, NC: North Central, NW: North Western, U: Uva, Sab: Sabaragamuwa.

DPDHS Divisions: CB: Colombo, GM: Gampaha, KL: Kalutara, KD: Kandy, ML: Matale, NE: Nuwara Eliya, GL: Galle, HB: Hambantota, MT: Matara, JF: Jaffna, KN: Killinochchi, MN: Mannar, VA: Vavuniya, MU: Mullaitivu, BT: Batticaloa, AM: Ampara, TR: Trincomalee, KM: Kalmunai, KR: Kurunegala, PU: Puttalam, AP: Anuradhapura, PO: Polonnaruwa, BD: Badulla, MO: Moneragala, RP: Ratnapura, KG: Kegalle.

Data Sources:

Weekly Return of Communicable Diseases: Diphtheria, Measles, Tetanus, Whooping Cough, Chickenpox, Meningitis, Mumps.

Special Surveillance: Acute Flaccid Paralysis.

Leishmaniasis is notifiable only after the General Circular No: 02/102/2008 issued on 23 September 2008.

National Control Program for Tuberculosis and Chest Diseases: Tuberculosis.

Table 3: Laboratory Surveillance of Dengue Fever

07th March - 13th March 2009 (11th Week)

Samples	Number tested	Number positive	Serotypes *				
			D1	D2	D3	D4	Negative
Number for current week	01	00	00	00	00	00	00
Total number to date in 2009	18	02	00	00	02	00	00

Sources: Genetic Laboratory, Asiri Surgical Hospital

* Not all positives are subjected to serotyping.

NA= Not Available.

Table 4: Selected notifiable diseases reported by Medical Officers of Health

07th March - 13th March 2009 (11th Week)

DPDHS Division	Dengue Fever / DHF*		Dysentery		Encephalitis		Enteric Fever		Food Poisoning		Leptospirosis		Typhus Fever		Viral Hepatitis		Human Rabies		Returns Received Timely**
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	%
Colombo	27	476	1	45	1	4	1	58	0	7	18	83	0	2	0	16	1	2	**100**
Gampaha	4	254	2	31	0	5	1	17	0	9	5	63	0	3	0	24	1	1	**79**
Kalutara	11	130	2	77	0	2	1	18	0	5	4	43	0	0	0	4	1	1	**92**
Kandy	29	449	6	79	0	1	0	8	2	50	0	53	1	30	0	11	0	0	**84**
Matale	19	144	1	23	0	0	1	13	0	5	6	121	0	2	0	2	0	1	**92**
Nuwara Eliya	0	17	19	83	0	0	1	50	0	20	0	15	0	15	3	12	0	0	**85**
Galle	2	27	3	47	1	6	0	0	0	2	0	42	0	1	0	6	1	3	**89**
Hambantota	2	38	0	25	1	6	0	2	0	4	0	14	1	24	0	4	0	0	**91**
Matara	6	154	7	80	0	2	0	4	0	3	4	45	2	46	1	4	0	0	**88**
Jaffna	1	7	0	26	0	3	2	59	0	19	0	0	2	72	0	5	0	1	**88**
Kilinochchi	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
Mannar	0	3	0	10	0	0	1	52	0	0	0	0	0	0	0	8	0	0	**50**
Vavuniya	0	4	3	27	0	0	0	2	0	1	0	2	0	0	0	0	0	0	**50**
Mullaitivu	0	0	0	2	0	0	0	1	0	0	0	0	0	0	0	0	0	0	**0**
Batticaloa	27	124	2	35	1	7	0	5	0	5	0	2	0	0	0	1	0	1	**64**
Ampara	0	22	0	8	0	0	0	5	0	0	1	6	0	0	0	4	0	0	**57**
Trincomalee	0	54	2	26	0	1	0	0	0	0	0	1	0	3	0	3	0	0	**90**
Kurunegala	10	189	2	43	0	3	0	14	0	1	2	31	0	40	4	16	0	3	**89**
Puttalam	6	41	4	35	0	5	6	34	0	0	8	24	3	20	0	2	0	1	**89**
Anuradhapura	23	52	2	23	1	2	1	2	0	2	0	56	1	16	0	4	0	0	**74**
Polonnaruwa	3	19	0	10	0	1	1	8	0	3	3	32	0	0	1	3	0	0	**86**
Badulla	1	20	4	66	0	2	0	13	0	13	1	29	1	19	5	66	0	0	**100**
Monaragala	1	9	0	13	0	0	0	7	0	2	0	5	1	25	1	13	0	0	**100**
Ratnapura	3	62	21	154	0	9	1	21	0	1	1	22	0	11	0	6	0	1	**72**
Kegalle	11	214	3	25	0	2	0	10	0	1	2	25	0	7	1	43	0	1	**82**
Kalmunai	2	68	1	42	0	1	0	5	1	1	0	2	0	1	0	3	0	0	**46**
SRI LANKA	**188**	**2577**	**85**	**1035**	**5**	**62**	**17**	**408**	**3**	**154**	**55**	**716**	**12**	**337**	**16**	**260**	**4**	**16**	**80**

Source: Weekly Returns of Communicable Diseases (WRCD).
*Dengue Fever / DHF refers to Dengue Fever / Dengue Haemorrhagic Fever.
**Timely refers to returns received on or before 13th March, 2009 Total number of reporting units =311. Number of reporting units data provided for the current week: 250
A = Cases reported during the current week. B = Cumulative cases for the year.

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